UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,768	07/13/2001	Florence L'Alloret	210578US0	1465

22850 7590 10/06/2003

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
YOON, TAE H	

ART UNIT	PAPER NUMBER
1714	

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/903,768	L'ALLORET ET AL.	
	Examiner	Art Unit	
	Tae H Yoon	1714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *29-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-28, drawn to an oil-in-water nanoemulsion and a method of using, classified in class 524 and 424, subclass 800+ and 78.03+, respectively.

II. Claims 29-33, drawn to a method for thickening an OIW nanoemulsion, classified in class 524, subclass 27+.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make othe materially different product by utilizing a cationic amphiphilic lipid as evidenced bu US Pat. 5,591,449, col. 7, lines 3-18, and because the claim 33 is broader than claim 1 and said claims are related as a combination and subcombination. Furthermore, the oil phase can be mixed with a water-soluble nonionic polymer and then mixed with an amphiphilic lipid.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, given

above and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. McIntyre on September 26, 2003 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-28. Affirmation of this election must be made by applicant in replying to this Office action. Claims 29-33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recited "derivatives" in line10 of claims 1 and 8 is indefinite I not specifying a particular substituent orfunctional group. The recited "their neutral derivatives" of claim 12 lacks an antecedent basis. The claim 1 is confusing since it is unclear which component(s) comprises an aqueous phase, especially in view of claim 28 wherein an

amphiphilic lipid is missing. Also, claim 28 is incomplete absent a step of contacting amphiphilic lipid.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12 and 14-28 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bollens et al (US 5,591,449).

Bollens et al teach oil-in water cosmetic and pharmaceutical emulsion compositions comprising an oil, an amphiphilic lipid and a polymer in examples. The use of an additional surfactant is taught at col. 5, lines 16-26. The vesicles (oil globules) are between 20 and 500 nanometer, in size, col. 7, lines 43-45. Various gelling agents

such as hydroxyethyl cellulose and their addition to the emulsion is taught at col. 8, lines 21-37. The composition of Bollens et al inherently possesses the recited viscosity and turbidity. Polymers recited in claims 6-11 are optional components when said claims 6-11 are combined with claim 1. Various compositions and active compounds taught at col. 4, lines 28-35 and col. 8, lines 5-20 inherently meet the recited ophthalmic vehicle of claims 21 and 27 absent further limitation.

Thus, the instant invention lacks novelty.

Claims 1-28 are rejected under 35 U.S.C. 103(a) as obvious over Bollens et al (US 5,591,449) in view of Friedman et al (US 6,004,566), Binns et al (US 6,287,377), Bernecker et al (US 6,569,414) or Suzuki et al (US 6,432,439), and further in view of FR 2 787 027 or Simonnet et al (US 6,274,150, 6,375,960 or 6,464,990).

The instant invention further recites various thickeners such as polyvinyl pyrrolidone, hydroxypropyl guar, polyethylene oxide or polyvinyl alcohol and turbidity. However, said polyvinyl pyrrolidone, hydroxypropyl guar, polyethylene oxide and polyvinyl alcohol are the art well known gelling or thickening agent as taught by Friedman et al (col. 6, lines 23-25), Binns et al (col. 8, lines 15-27), Bernecker et al (col. 4, lines 5-8) and Suzuki et al (col. 8, lines 1-5). Also, the instant turbidity is well known in oil-in water cosmetic and pharmaceutical emulsion compositions as taught by FR (page 2, lines 30-40) and Simonnet et al (top of col. 3 in US'150 and '960 and col. 3, lines 25-30 of US'990).

It would have been obvious to one skilled in the art at the time of invention to utilize the thickeners taught by Friedman et al, Binns et al, Bernecker et al or Suzuki et al in Bollens et al since Bollens et al teach employing gelling or thickening agent and since the recited nonionic polymers are the art well known gelling or thickening agent, and further to make a composition having the instant size of oil globules and turbidity in Bollens et al thereof with teaching of FR or Simonnet et al since Bollens et al teach 20-500 nm and since oil-in water cosmetic and pharmaceutical emulsion compositions having the instant turbidity is well known in the art.

Claims 1-12, 14-16 and 18-28 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over FR 2787027.

FR teaches oil-in water cosmetic and pharmaceutical nanoemulsion compositions comprising an oil and an amphiphilic lipid in abstract and examples and at page 2, lines 30-40. The use of gelling agents, such as cellulose derivatives which are nonionic, is taught at page 8, line 24. Thus, the instant invention lacks novelty.

Claims 1-12, 14-16 and 18-28 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Simonnet et al (US 6,464,990).

Simonnet et al teach oil-in water cosmetic and pharmaceutical nanoemulsion compositions comprising an oil, an amphiphilic lipid and a block copolymer of ethylene

oxide and propylene oxide in abstract and examples. Said block copolymer meets the instant water-soluble nonionic polymer. Thus, the instant invention lacks novelty.

Claims 1-12, 14-16 and 18-28 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Simonnet et al (US 6,274,150 or 6,375,960).

Two patents are almost same and the examiner points out US 6375,960. Simonnet et al teach oil-in water cosmetic and pharmaceutical nanoemulsion compositions comprising an oil and an amphiphilic lipid in abstract and examples. The use of gelling agents, such as cellulose derivatives which are nonionic, is taught at col. 7, lines 32-36. Thus, the instant invention lacks novelty.

Claims 1-28 are rejected under 35 U.S.C. 103(a) as obvious over Simonnet et al (US 6,274,150 or 6,375,960 or 6,464,990) or FR 2787027 in view of Friedman et al (US 6,004,566), Binns et al (US 6,287,377), Bernecker et al (US 6,569,414) or Suzuki et al (US 6,432,439).

Simonnet et al teach employing gelling agents (col. 6, lines 26-30 of US'990, col. 7, lines 32-36 of US'960 and col. 6, lines 17-21of US'150), and FR teaches the same.

The instant invention further recites various thickeners such as polyvinyl pyrrolidone, hydroxypropyl guar, polyethylene oxide or polyvinyl alcohol. However, said polyvinyl pyrrolidone, hydroxypropyl guar, polyethylene oxide and polyvinyl alcohol are the art well known gelling or thickening agent as taught by Friedman et al (col. 6, lines

23-25), Binns et al (col. 8, lines 15-27), Bernecker et al (col. 4, lines 5-8) and Suzuki et al (col. 8, lines 1-5).

It would have been obvious to one skilled in the art at the time of invention to utilize the gelling or thickening agent taught by Friedman et al, Binns et al, Bernecker et al or Suzuki et al in Simonnet et al or FR since Simonnet et al and FR teach employing gelling or thickening agent which is well known in the art.

Claims 1-12 and 14-28 are rejected under 35 U.S.C. 103(a) as obvious over Suzuki et al (US 6,432,439) in view of Bollens et al (US 5,591,449).

Suzuki et al teach oil-in water pharmaceutical emulsion compositions comprising an oil, an amphiphilic lipid and a polymer in examples (for example see table 1). Various applications and nonionic, water-soluble cellulose derivatives are taught at cols. 3-4. Various phospholipids and an amount of thereof are also taught at col. 5, line 45 to col. 7, line 37, and example 1 shows a mixture of phospholipids. The addition of said nonionic, water-soluble cellulose derivative in the thin lipid membrane is taught at col. 9, lines 1-25. The use of other thickening agent is taught at col. 7, line 66 to col. 8, line 5 and in the preparation examples (col. 18, line 43, for example). The composition of Suzuki et al inherently possesses the recited viscosity and turbidity.

The instant invention further recites the size of oil globules. However, the instant size is well known in the oil-in water cosmetic and pharmaceutical emulsions as taught by Bollens et al.

It would have been obvious to one skilled in the art at the time of invention to make oil-in water pharmaceutical emulsion compositions having the instant size of oil globules in Suzuki et al with teaching of Bollens et al since the instant size is well known in the oil-in water cosmetic and pharmaceutical emulsions and since Suzuki et al teach filtration (col. 8, line 31 and col. 18, lines 59-60).

Claims 1-28 are rejected under 35 U.S.C. 103(a) as obvious over Suzuki et al (US 6,432,439) and Bollens et al (US 5,591,449) and further in view of Friedman et al (US 6,004,566) or Binns et al (US 6,287,377) and further in view of FR 2 787 027 or Simonnet et al (US 6,274,150, 6375,960 or 6,464,990).

The instant invention further recites various thickeners such as hydroxypropyl guar or polyethylene oxide and turbidity over Suzuki et al and Bollens et al. However, said hydroxypropyl guar and polyethylene oxide are the art well known gelling or thickening agent as taught by Friedman et al (col. 6, lines 23-25), and Binns et al (col. 8, lines 15-27). Also, the instant turbidity is well known in oil-in water cosmetic and pharmaceutical emulsion compositions as taught by FR (page 2, lines 30-40) and Simonnet et al (top of col. 3 in US'150 and '960 and col. 3, lines 25-30 of US'990).

It would have been obvious to one skilled in the art at the time of invention to utilize the thickeners taught by Friedman et al or Binns et al in Suzuki et al and Bollens et al since Suzuki et al teach employing gelling or thickening agent and since the recited nonionic polymers are the art well known gelling or thickening agent, and further to make a composition having the instant size of oil globules and turbidity in Suzuki et al

thereof with teaching of FR or Simonnet et al since oil-in water cosmetic and pharmaceutical emulsion compositions having the instant turbidity is well known in the art.

Claims 1-28 are rejected under 35 U.S.C. 103(a) as obvious over EP 0 728 460 in view of Friedman et al (US 6,004,566), Suzuki et al (US 6,432,439) or Binns et al (US 6,287,377) and further in view of FR 2 787 027 or Simonnet et al (US 6,274,150, 6375,960 or 6,464,990).

EP teaches oil-in water cosmetic nanoemulsion compositions comprising an oil and an amphiphilic lipid in examples and at col. 3, lines 9-41. EP also teaches employing gelling agents such as cellulose derivatives at col. 5, lines 4-14.

The instant invention further recites various thickeners such as methylcellulose, hydroxypropyl guar or polyethylene oxide and turbidity over EP. However, said methylcellulose, hydroxypropyl guar and polyethylene oxide are the art well known gelling or thickening agent as taught by Suzuki et al (col. 3, line 56), Friedman et al (col. 6, lines 23-25), and Binns et al (col. 8, lines 15-27). Also, the instant turbidity is well known in oil-in water cosmetic emulsion compositions as taught by FR (page 2, lines 30-40) and Simonnet et al (top of col. 3 in US'150 and '960 and col. 3, lines 25-30 of US'990).

It would have been obvious to one skilled in the art at the time of invention to utilize the thickeners or gelling agents taught by Friedman et al, Binns et al or Suzuki et al in EP since EP teaches employing gelling or thickening agent and since the recited

nonionic polymers are the art well known gelling or thickening agent, and further to make a composition having the instant turbidity in EP thereof with teaching of FR or Simonnet et al since oil-in water cosmetic emulsion compositions having the instant turbidity is well known in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tae H Yoon whose telephone number is (703) 308-2389. The examiner can normally be reached on Mon-Thu.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (703) 306-2777. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Tae H Yoon
Primary Examiner
Art Unit 1714

THY/September 29, 2003